Xdemvy access in Saudi Arabia: the SFDA Personal Importation Program

How patients in the Kingdom of Saudi Arabia access Xdemvy (lotilaner ophthalmic solution 0.25%) for adult Demodex blepharitis.

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team.

1. Quick orientation

Xdemvy is the brand name for lotilaner ophthalmic solution 0.25%, a topical ophthalmic small-molecule ectoparasiticide developed and commercialised by Tarsus Pharmaceuticals. The mechanism is selective antagonism of the Demodex mite gamma-aminobutyric acid-gated chloride (GABA-Cl) channel, which produces parasiticidal effect against the mite rather than treating downstream inflammation alone. The US Food and Drug Administration approved Xdemvy on July 25, 2023 for the treatment of Demodex blepharitis in adults under NDA 217603. It is the first and only FDA-approved therapy that directly targets the underlying mite infestation. In the Kingdom of Saudi Arabia, the Saudi Food and Drug Authority (SFDA) has no confirmed local marketing authorisation for Xdemvy as of May 2026, and no equivalent locally registered Demodex-blepharitis parasiticide is on the Kingdom market. Saudi patients with chronic, recalcitrant Demodex blepharitis confirmed on slit-lamp examination reach Xdemvy through the SFDA Personal Importation Program (PIP). Reserved for you.

2. Why Saudi Arabia patients need Xdemvy via the named-patient pathway

Three patterns of access gap apply across the Kingdom: a drug is registered with SFDA but not stocked at the treating hospital on the day the patient needs it; a drug is registered with SFDA for one indication but the physician is prescribing it for a different FDA-approved indication that has not been added to the local label; or a drug is FDA-approved but the manufacturer has never sought SFDA registration. Xdemvy sits in the third pattern. No equivalent parasiticidal ophthalmic product carries a regulator-endorsed Demodex blepharitis indication anywhere in the Kingdom, and local ophthalmology has historically relied on lid hygiene, hypochlorous acid sprays, tea tree oil derivatives, and off-label antiparasitics.

Three named-patient demand patterns repeat in the Kingdom's ophthalmology community. First, prevalence: Demodex blepharitis is highly prevalent globally and is estimated to account for roughly two-thirds of all blepharitis cases worldwide, with a substantial Saudi adult patient population. Second, no equivalent locally registered option: Xdemvy is the first and only FDA-approved drug that directly targets the underlying Demodex mite, and no equivalent locally registered parasiticidal ophthalmic product exists in the Kingdom. Third, treatment-refractory cases: patients pursuing Xdemvy through the PIP typically present with chronic, recalcitrant Demodex blepharitis confirmed on slit-lamp examination (collarettes at the base of the lashes), have failed adjunctive measures (lid hygiene, hypochlorous acid sprays, tea tree oil products, microblepharoexfoliation), and have an ophthalmologist willing to write the cross-border prescription.

The clinical setting is distinct from the oncology and rare-disease patterns that dominate cross-border named-patient activity. Xdemvy cases are typically lower acuity than oncology cases. The regulatory pathway, however, is the same: physician-issued prescription, SFDA PIP documentation, DSCSA-compliant US specialty sourcing, ambient shipment, and dispensing-site confirmation on receipt. The finite 6-week course means most cases are single-shipment, which simplifies coordination relative to chronic monthly cadence products.

3. The SFDA Personal Importation Program for Xdemvy

The SFDA Personal Importation Program allows a Kingdom-licensed physician to request import of a specific medicine for a specific named patient when the medicine is approved by a recognised reference authority (typically the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally registered alternative is not suitable for the patient. The framework explicitly contemplates specialty therapies for which no equivalent locally registered indication exists, which is exactly the Xdemvy case. Applications are filed through the dispensing institution's import pharmacy and reviewed by SFDA's Drug Sector, with activity increasingly routed through the Ghad digital platform alongside the agency's English portal at sfda.gov.sa.

A complete PIP application for Xdemvy includes the clinical justification letter from the treating ophthalmologist or optometrist with prescribing privileges; the treating physician's licensing verification through the Saudi Commission for Health Specialties (SCFHS) in ophthalmology; the patient identifier in the format SFDA requires for the named-patient case file; full product details (Xdemvy, lotilaner ophthalmic solution 0.25%, Tarsus Pharmaceuticals, 5 mL multi-dose bottle, two bottles per 6-week course); the destination dispensing facility license; and a chain-of-custody plan for ambient shipment from the US point of release through international transit to the receiving Saudi pharmacy.

The clinical-justification angle for Xdemvy turns on slit-lamp documentation of collarettes and prior-line therapy failure. The treating ophthalmologist documents the slit-lamp examination findings (collarettes at the base of the lashes, the hallmark of Demodex blepharitis), the chronicity of symptoms, the prior adjunctive therapies attempted (lid hygiene with tea tree oil derivatives, hypochlorous acid lid sprays, in-office microblepharoexfoliation, off-label antiparasitics) and their outcomes, and the rationale for sourcing the only directly indicated FDA-approved product. The application states the planned 6-week course (one drop in each eye, twice daily, approximately 12 hours apart) and the rationale for the finite course. Approval timelines for routine SFDA cases run 10 to 21 business days, with the simpler regulatory profile of a topical ophthalmic ambient product generally tracking the low end of the range.

4. Where Xdemvy gets dispensed in Saudi Arabia

Xdemvy is a sterile topical ophthalmic solution, room-temperature stable with permitted excursions between 15 and 30 degrees Celsius. Refrigeration at 2 to 8 degrees Celsius is permitted but not required. There is no reconstitution step, no cold chain, and no infusion infrastructure. The dispensing requirement is therefore an SFDA-licensed hospital outpatient pharmacy, specialty ophthalmology clinic pharmacy, or specialty import pharmacy aligned with an ophthalmology service. Tamper-evident specialty pharmacy packaging is retained through the international leg, and the destination ophthalmologist or pharmacy confirms intact packaging on receipt.

Kingdom institutions with ophthalmology services that handle named-patient imports as routine workflow include King Khaled Eye Specialist Hospital (KKESH) in Riyadh, the national tertiary ophthalmology referral centre with comprehensive subspecialty programs; King Faisal Specialist Hospital and Research Centre (KFSH&RC) in Riyadh, Jeddah, and Madinah, with ophthalmology services and experienced in-house import pharmacy; King Abdulaziz Medical City (KAMC) and the Ministry of National Guard Health Affairs (MNGHA) network; Dr. Sulaiman Al Habib Medical Group (HMG), the largest private hospital network in the Kingdom with multiple eye and refractive services across Riyadh, Jeddah, and the Eastern Province and routine PIP activity through their import pharmacy operations; Saudi German Hospital; Dr. Soliman Fakeeh Hospital in Jeddah; and Dallah Hospital in Riyadh. For ophthalmologists at smaller practices, the typical pattern is to partner with an SFDA-licensed specialty importer based in Riyadh or Jeddah that handles the PIP filing.

5. Real cost picture for Xdemvy in Saudi Arabia

The Saudi riyal is pegged at approximately 3.75 SAR to 1 USD, which makes the dollar-denominated US wholesale acquisition cost the principal driver of the case economics. Xdemvy is positioned as a mid-tier specialty product, one to two orders of magnitude below per-course pricing for advanced oncology biologics or rare-disease enzyme replacement therapies. Three line items frame the cost.

First, drug cost. The US wholesale acquisition cost range for a complete 6-week course of Xdemvy (10 mL total, two 5 mL bottles) is approximately USD 1,850 to USD 2,034 at the cash list price (roughly SAR 6,950 to SAR 7,650 per course), per pharmacy pricing aggregators including GoodRx and pharmacy-pricing trade references in 2026. A single 5 mL bottle list price runs approximately USD 600 to USD 1,000 depending on the pharmacy and date of the price reference. Tarsus-branded US-only copay assistance does not extend to international patients.

Second, international logistics. Xdemvy is room-temperature stable and ships under ambient conditions with no gel packs, dry ice, or active temperature loggers required. International logistics for an ambient ophthalmic shipment to the Kingdom typically runs SAR 1,500 to SAR 3,750 (approximately USD 400 to USD 1,000) depending on city of delivery and urgency window.

Third, regulatory and coordination. SFDA documentation handling fees and Reserve Meds' concierge fee are itemised separately. On the insurance side, Bupa Arabia, Tawuniya (The Company for Cooperative Insurance), and MedGulf Arabia handle named-patient imports case by case. Coverage of an ophthalmic specialty product without a locally registered indication is typically discretionary; cash-pay is the default operating posture and the relative affordability of the 6-week course (one or two orders of magnitude below oncology biologics) keeps the case feasible for many private patients. Reserve Meds quotes an indicative range based on the initial intake, then a transparent firm quote with each line item shown separately.

6. Typical timeline for Xdemvy in Saudi Arabia

The SFDA timeline for routine PIP cases runs 10 to 21 business days. Xdemvy is an ambient ophthalmic product, so cold-chain transit time does not apply, and the regulatory profile of a topical specialty therapy with a finite 6-week course typically tracks the low end of the range. End-to-end, a typical Xdemvy case in the Kingdom runs as follows: 24 to 48 hours from intake to eligibility confirmation by Reserve Meds; 3 to 5 days for the treating ophthalmologist and the dispensing pharmacy or specialty importer to assemble the application with slit-lamp documentation; 10 to 21 business days for SFDA review; 3 to 5 days for US sourcing through Tarsus's contracted specialty pharmacy network and qualified ambient shipment with full DSCSA-compliant chain-of-custody and tamper-evident packaging retained through the international leg; 1 to 3 days for Saudi customs clearance under the PIP permit; and final receipt and release at the dispensing pharmacy. Because the 6-week course is typically a single-shipment case, repeat-shipment cadence is not built into the first case unless the treating ophthalmologist plans a second course for recurrence.

7. What your physician needs to provide

The clinical justification letter is the cornerstone of the SFDA PIP application. The treating Kingdom ophthalmologist documents the patient's diagnosis of Demodex blepharitis in an adult patient, with confirmation that the patient is aged 18 years or older (Xdemvy is not approved for pediatric patients under 18); states the slit-lamp examination findings (collarettes at the base of the lashes, the hallmark of Demodex blepharitis) with photographic documentation where available; documents the chronicity of symptoms (typically months to years of recalcitrant blepharitis); itemises prior adjunctive therapies attempted (lid hygiene with tea tree oil derivatives, hypochlorous acid lid sprays, in-office microblepharoexfoliation, off-label antiparasitics) and their outcomes; explains why a locally registered alternative is not suitable, with the structural answer that no equivalent parasiticidal ophthalmic product carries a regulator-endorsed Demodex blepharitis indication in the Kingdom; states the planned dosing regimen (one drop in each eye, twice daily, approximately 12 hours apart, for 6 weeks, continued for the full course even if symptoms resolve earlier); and describes the minimal monitoring plan.

The monitoring stack is light. There are no required laboratory studies, no required electrocardiogram, and no required pre-treatment screening assays. Clinical follow-up is on the prescriber's standard ophthalmology cadence, typically a check at the end of the 6-week course to evaluate collarette resolution and symptom response. Administration mechanics from the package insert are documented: wash hands before instillation; remove contact lenses prior to instillation and wait at least 15 minutes before reinsertion; avoid bottle tip contact with the eye or eyelid; continue the full 6-week course. The letter is

co-filed with the physician's SCFHS license verification, the institutional pharmacy license, and the chain-of-custody plan for the ambient shipment.

8. Common questions about Xdemvy in Saudi Arabia

Will Bupa Arabia, Tawuniya, or MedGulf cover Xdemvy? Each plan handles named-patient imports case by case. Coverage of an ophthalmic specialty product without a locally registered indication is typically discretionary, but the relative affordability of the 6-week course keeps the case feasible for many private patients on a cash-pay basis. We do not promise coverage from any insurer.

Will my ophthalmologist's letter be sufficient? Yes. KSA-licensed ophthalmologists at Ministry of Health hospitals, KKESH, KFSH&RC, KAMC, MNGHA, and other public-sector institutions have full signing authority on PIP applications. Private-sector ophthalmologists at HMG, Saudi German, Fakeeh, Dallah, and similar institutions also have signing authority under their institutional license.

Can my optometrist prescribe Xdemvy? The PIP application is physician-license-tied and is typically signed by an ophthalmologist with SCFHS registration. Optometrist scope of practice in the Kingdom does not generally include prescribing imported medicines under PIP, so the case is co-signed by a partnering ophthalmologist.

What is the safety profile I should know about? The Saturn-1 and Saturn-2 pivotal phase 3 trials enrolled more than 800 patients combined and reported no serious treatment-related adverse events. The most common adverse reaction was instillation site stinging and burning, reported in approximately 10 percent of patients. Other ocular adverse reactions including chalazion or hordeolum and punctate keratitis were reported in less than 2 percent of patients.

How long until I know if it is working? The 6-week course is finite. Most patients see collarette and symptom improvement by the end-of-course visit. There is no defined re-treatment interval in the label, and decisions on a second course in cases of recurrence are made by the treating ophthalmologist on a case-by-case basis.

Why this drug versus tea tree oil or lid hygiene? The clinical rationale is mechanism specificity. Lid hygiene reduces bacterial load and debris, tea tree oil has variable anti-mite activity with significant tolerability concerns at therapeutic concentrations, and neither demonstrates the collarette cure and mite eradication rates documented for lotilaner in randomised vehicle-controlled trials. The decision rests with the treating ophthalmologist; Reserve Meds does not endorse one regimen over another.

9. Where Reserve Meds fits in Xdemvy cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating ophthalmologist, SFDA, the dispensing pharmacy or specialty importer, or your insurer. What we do for an Xdemvy case is verify eligibility within 24 to 48 hours; supply your physician's team with a documentation kit referencing the FDA prescribing information, the twice-daily 6-week regimen, the slit-lamp collarette framing, and the minimal monitoring profile; align US-side sourcing through Tarsus's contracted specialty pharmacy network under DSCSA-compliant chain-of-custody with tamper-evident specialty pharmacy packaging retained through the international leg; coordinate ambient shipment with a qualified specialty 3PL; and provide a single named Patient Concierge Coordinator across the case. Because Xdemvy is a finite-course topical ophthalmic with a simple ambient logistics profile, most cases are single-shipment, and the case complexity sits in the regulatory and documentation side rather than in physical logistics. No prior Reserve Meds case experience predates this page; standard NPP coordination applies.

10. Next step

If your Kingdom ophthalmologist has documented collarettes on slit-lamp examination and recommends Xdemvy, start the request and we will reach out within 24 to 48 hours.

Reserved for you.

Review & oversight. Content on this page is reviewed by Reserve Meds's clinical and regulatory team. A US-licensed pharmacist reviews every prescription before dispensing. Regulatory posture is informational, not legal advice; case-specific questions route to retained outside counsel. Review methodology ›

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